DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 12, 2015

Art Optical Contact Lens, Inc.
% Mr. Bret Andre
Official Correspondent
EyeReg Consulting, Inc.
474 NE 61st Place
Hillsboro, Oregon 97124

Re: K142641
Trade/Device Name: Intelliwave4
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 4, 2014
Received: December 8, 2014

Dear Mr. Andre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142641

Device Name
Intelliwave4, Silicone Hydrogel Daily Wear Soft Contact Lens (safrofilcon A)

Indications for Use *(Describe)*
The Intelliwave4, sphere (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The Intelliwave4, toric (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The Intelliwave4, multifocal (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The IntelliWave4, multifocal toric (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The IntelliWave4, irregular cornea (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

IntelliWave4 UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system or hydrogen peroxide disinfection systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**The assigned 510(k) number is:** **K142641**

**Applicant information:**

| | |
|---|---|
| Date Prepared: | October 20th , 2014 |
| Name: | Art Optical Contact Lens, Inc. |
| Address | 3175 3 Mile Road NW<br>Walker, Michigan 49534 |
| Contact Person: | Mike Johnson, FCLSA<br>Director of Consultative Services |
| Phone number: | (616) 559-5167 |
| Consultant: | Bret Andre<br>EyeReg Consulting, Inc.<br>474 NE 61st PL<br>Hillsboro, OR 97124 |
| Phone number | (503) 372-5226 |

**Device Information:**

| | |
|---|---|
| Device Classification: | Class II |
| Product Code: | LPL |
| Classification Name: | Soft (hydrophilic) Contact Lens (21 CFR 886.5925) |
| Trade Name: | **Intelliwave4, Silicone Hydrogel Daily Wear Soft Contact Lens (safrofilcon A)** |

**Equivalent Devices:**

The **Intelliwave4,** Silicone Hydrogel Daily Wear Soft Contact Lenses (safrofilcon A) are substantially equivalent to the following predicate devices:

*Predicate devices:*

"**IntelliWave$^3$ (efrofilcon A)**"
by Art Optical Contact Lens, Inc.
510(k) number; **K100221**

**Device Description:**

The **Intelliwave4** Silicone Hydrogel Soft Contact Lenses are fabricated from safrofilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material (safrofilcon A) is a daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers and optionally incorporates Reactive Blue 246 (21 CFR 73.3106) as an integrated handling tint. The lenses are made by lathe-cut for custom RX. It consists of 35% safrofilcon A and 65% water by weight when immersed in a buffered saline solution. The (safrofilcon A) name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (safrofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

UV Absorber:
In the **Intelliwave4** Contact Lens with UV Blocker and center thickness of 0.18mm, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV Blocker is 2-(4-Benzoyl-3-hydroxyphenoxy)ethyl acrylate. The UV blocking for **Intelliwave4** lenses averages > 99% in the UVB range of 280nm – 315nm and >77% in the UVA range of 316 – 380nm.

The Physical properties of the lens are:

| | |
|---|---|
| **Refractive Index (wet)** | 1.3841 |
| **Visible Light Transmission** | >98% |
| **Surface Character** | hydrophilic |
| **Water Content** | 65 % |
| **Specific Gravity** | 1.102 (hydrated) |
| **Oxygen Permeability** | 46.46 x $10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x hPa @ $35^oC$), (revised Fatt method). |

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 65% water by weight. The lenses will be manufactured in spherical, aspherical, toric, and multifocal configurations with the following features and properties.

| | |
|---|---|
| • Chord Diameter | 12.0 mm to 16.00 mm |
| • Center Thickness | 0.01 mm to 0.50 mm |
| • Base Curve | 8.0 mm to 9.5 mm |
| • Power Range | -20.00D to +20.00D in 0.25 steps |
| • Cylinder Power (Toric) | -0.25D to -10.00D |
| • Add Power (Multifocal) | +0.50D to +3.00D |

The lens is supplied sterile in vials containing a buffered saline solution. Vial labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

**Intended Use:**

The **Intelliwave4,** sphere (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **Intelliwave4,** toric (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters.

The **Intelliwave4,** multifocal (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 12 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave4,** multifocal toric (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave4**, irregular cornea (safrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

**IntelliWave4** UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system or hydrogen peroxide disinfection systems.

**Testing:**

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **IntelliWave4** (safrofilcon A) Silicone Hydrogel Soft Contact Lenses packaged in glass vials. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols.

Test results of the non-clinical testing on the **IntelliWave4** (safrofilcon A) Silicone Hydrogel Soft Contact Lenses demonstrate that:

- Lenses supplied in glass vials are sterile for the indicated shelf-life,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

A bilateral, open-label, parallel group, and randomized daily wear study was performed to evaluate the safety and efficacy of the **IntelliWave4** (safrofilcon A) Silicone Hydrogel Soft Contact Lens. The study evaluated 60 patients over a three (3) months period. Clinical evaluation demonstrated similar overall performance to the concurrent predicate control in the clinically relevant areas of vision, health, and comfort and fit when worn for daily wear.

**Conclusions Drawn from Studies**

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, Microbiology, chemistry, shelf-life stability studies and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **IntelliWave4,** (safrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of Silicone Hydrogel, Daily Wear Soft Contact Lens. The benefits to the patient are the same as those for other Silicone Hydrogel contact lenses.

**Substantial Equivalence:**

The following matrix illustrates the production method, lens function and material characteristics of the **Intelliwave4,** (safrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, as well as the predicate devices.

# Substantial Equivalence Matrix

| | **Art Optical IntelliWave4, Silicone Hydrogel (safrofilcon A) New Device** | **Art Optical IntelliWave[3], Silicone Hydrogel (efrofilcon A) Predicate Device 510(k) K100221** |
|---|---|---|
| **Intended Use** | Indicated for daily wear for the correction of visual acuity in aphakic and not apjakic persons with non-diseased eyes with myopia or hyperopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting. | Indicated for daily wear for the correction of visual acuity in aphakic and not apjakic persons with non-diseased eyes with myopia or hyperopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting. |
| **Functionality** | Same as predicate device | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina |
| **Indications** | Daily wear. Silicone Hydrogel Soft (hydrophilic) contact lens | Daily wear. Silicone Hydrogel Soft (hydrophilic) contact lens |
| **Production Method** | Lathe-Cut, custom manufactured | Lathe-Cut, custom manufactured |
| **USAN name** | safrofilcon A | efrofilcon A |
| **Water Content (%)** | 65% | 74% |
| **Oxygen Permeability** | 46.46 x $10^{-11}$ (cm2/sec) (ml O2/ml x hPa @ 35oC), (revised Fatt method) | 60 x $10^{-11}$ (cm2/sec) (ml O2/ml x hPa @ 35oC), (revised Fatt method) |
| **Specific Gravity** | 1.102 | 1.139 |